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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/069,703	04/29/1998	GILLES H. TAPOLSKY	BSZ-092CPRCE	3665

959 7590 12/20/2007
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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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12/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/069,703

Applicant(s)

TAPOLSKY ET AL.

Examiner

Edward J. Webman

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,12,13,15-18,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9,12,13,15-18,33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/5/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

The notice of non-responsive amendment filed 11/15/07 is withdrawn because it inadvertently addressed claims in a copending case. The following rejection is adapted from the final rejection of Examiner M. Graffeo filed 7/16/06 in previously copending case 09/684682, now abandoned, containing claims directed to a method of using a composition overlapping in scope with the instant claims.

Claims 1-3, 5-8, 12, 15-18, 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,765,983 to Takayanagi et al. in view of US Patent No. 4,594,240 to Kawata et al, WO 95/05416 (WO '416) and EPA 250187 (EPA '187).

Takayanagi et al. teach adhesive medical tapes for oral mucosa comprising a support layer composed of an intestine-soluble polymer and a medicament-containing layer composed of a water-soluble polymer containing at least one kind of a steroid or non-steroid antiphlogistic and analgesic medicament (see Abstract), and further comprising a water-soluble polymer such as polyvinylpyrrolidone, sodium carboxymethyl cellulose, hydroxypropyl cellulose (see column 2 lines 57-end), hydroxypropylmethyl cellulose (col 3 line 45) and hydroxymethylethyl cellulose (column 3 line 46) and wherein the thickness of the medicament containing layer (which is two layers) is more than 200um and at most 3000um [which is equivalent to 0.02-0.3mm] (see column 3 lines 5-18). Water is disclosed (column 6 example 2).

Kawata et al. teach the use of hydroxyethyl cellulose and polyacrylic acid in the flexible pharmaceutical containing sheet (see column 1 lines 4-10).

WO '416 teaches overlaying an adhesive layer to prevent leakage of active from edges (page 30 lines 16-24).

EPA '187 teaches an intra-oral film (Title). Flavors are disclosed as customary (page 4, lines 41-43).

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine Takayanagi et al. and Kawata et al. because Takayanagi et al cite Kawata et al. and further since both are directed to pharmaceutical carrying sheet shaped muco-adhesives. Thus, the combined references teach and make *prima facie* obvious how to use the claimed invention at the time that it was made. As to the claimed percent solvent, such must be possessed by the obvious composition because it is the same as that claimed. It would have been further obvious to one of ordinary skill to overly an adhesive layer in Takyanagi et al to achieve the beneficial effect of preventing leakage of active from edges in view of WO '416 and to add a flavor as a customary additive in intra-oral films in view of EPA '187. As to the claimed dyclonine, the active is well-known in the art as a topical anesthetic. Thus, it would be obvious to one of ordinary skill to add it to the obvious composition to provide a second mode to that of analgesics in relieving pain.

Claims 1-3, 5-9, 12-13, 15, 34 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 and 13 it is unclear as to

whether "water-erodible" is intended before "bioadhesive polymer". Similarly, in claim 14 it is unclear whether "water-erodible" is intended before both "film-forming polymer" and "bioadhesive polymer". In contrast, see claims 10, 16, 17 and 33.

Claims 1-3, 5-9, 12-13, 15-18, 33-34 are rejected. Claim 10 is allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 9/5/07 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


EDWARD J. WEBMAN
PATENT EXAMINER
GROUP 1800